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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,777	09/26/2001	Robert S. Kieval	1151.1106101	1758
20350	7590	11/04/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			OROPEZA, FRANCES P	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,777

Applicant(s)

KIEVAL ET AL.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/22/04 (Election).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 10, 12, 14, 22, 24, 26, 33, 34, 37, 38, 44 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-9, 11, 13, 15-21, 23, 25, 27-32, 35, 36, 39-43, 45 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date See Office Action.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/ Restriction

1. Claims 4, 5, 10, 12, 14, 22, 24, 26, 33, 34, 37 and 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/22/04.
2. Previously submitted claims 44 and 46 directed to a species invention of figures 23 and 26 respectively were indicated as being elected by the Applicant. Since the Applicant elected to prosecute the third species (Figures 22E and 22F) and the sixth species (Figure 25), claims 44 and 46 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3, 6, 7, 11, 13, 15, 18, 20, 25, 27, 28, 31, 39, 42 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieval et al. (US 6073048) in view of Schwartz et al. (US3522811).

Kieval et al. disclose neural stimulation of the carotid sinus in the area of the carotid bodies (figure 148, 149), read to include the area extending from the internal and external carotid arteries, through the bifurcation of the carotid artery and to the common carotid artery. The nerve electrode described in US 3522811 to Schwartz is recommended by Kieval et al. (figure 7: col. 1 @ 60 – col. 3 @ 4; col. 5 @ 35-39; col. 6 @ 6-11).

As discussed in the previous paragraph of this action, Kieval et al. disclose the claimed invention except for the activation device having a base and a plurality of electrodes mounted parallel to the base, the activation device mounted orthogonal to the nerve.

Schwartz et al. teaches nerve stimulation using the activation device having a base and a plurality of electrodes mounted parallel to the base, the activation device mounted orthogonal to the nerve for the purpose of stimulating to carotid nerve. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the activation device having a base and a plurality of electrodes mounted parallel to the base, the activation device mounted orthogonal to the nerve in the Kieval et al. system because it is suggested by Kieval et

al. and it enables use of an electrode configuration proven to stimulate the baroreflex system of the patient.

5. Claims 8, 9, 16, 17, 21, 23, 29, 30, 32, 35, 36, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieval et al. (US 6073048) in view of Schwartz et al. (US3522811) and further in view of Woloszko et al. (US 5938596). As discussed in paragraph 4 of this action, modified Kieval et al. disclose the claimed invention except the activation device comprising more than two electrodes (claims 8, 21, 32), and the electrodes covering less than 50%/ 180 degrees or 25%/ 90 degrees of the circumference of the carotid sinus (claims 16, 17, 29, 30, 40, 41).

Woloszko et al. teach activation device customization using more than two electrodes (figure 4A- 10,11,12) and having the electrode vary in length including covering less than 50%/ 180 degrees or 25%/ 90 degrees of the circumference of the a neural stimulation location for the purpose of providing patient appropriate electrical stimulation of neural tissue. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used more than two electrodes (figure 4A) and having the electrode vary in length including covering less than 50%/ 180 degrees or 25%/ 90 degrees of the circumference of the carotid sinus in the modified Kieval et al. system in order to enable customization and self sizing of the activation device to accommodate nerve swelling and prevent nerve damage while maintaining nerve contact (figure 4A; col. 3 @ 40-46; col. 4 @ 3-24).

6. Claims 19, 43 and 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kieval et al. (US 6073048) in view of Schwartz et al. (US3522811) and further in view of Kieval (US 6178349). As discussed in paragraph 4 of this action, modified Kieval et al. ('048) disclose the claimed invention except for the structural integrity of the base (claims 19 and 43) and the activation device being sutured (claim 47).

As to base integrity, Kieval ('349) teaches electrode construction utilizing an activation device with a base having sufficient structural integrity to grasp the nerve for the purpose of sustaining long-term contact between the nerve and the electrode. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an activation device with a base having sufficient structural integrity to grasp the nerve a suture in the modified Kieval et al. ('048) system in order ensure the activation device remains in the proper location so patient treatment can be given efficiently and effectively, avoiding the risk and expense of future surgery to correct a misplaced neural stimulation electrode (col. 5 @ 45-55).

As to a suture, Kieval ('349) teaches electrode stabilization using sutures for the purpose of securing the electrode in its anatomical location. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a suture in the modified Kieval et al. ('048) system in order provide means to ensure the activation device remains in the proper location so patient treatment can be given efficiently and effectively, avoiding the risk ad expense of future surgery to correct a misplaced neural stimulation electrode (col. 5 @ 55-58).

Information Disclosure Statements

7. The Information Disclosure Statements attached to this office action were filed: 1/14/02, 4/22/02, 2/14/03, 8/18/03, 10/20/03, 2/10/04 and 2/11/04.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frances P. Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on (703) 308-5181. The telephone number for facsimiles for regular communication and After Final communications is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
10/29/04

Angela D. Sykes

ANGELA D. SYKES
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